IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

James W. Schumm, et. al.

Serial No.

Filed:

I, Diane J. Frauchiger, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the date of my signature.

Diane J. Frauchiger
Signature

February 15, 2001
Date of Signature

"MATERIALS AND METHODS FOR IDENTIFYING AND ANALYZING INTERMEDIATE TANDEM REPEAT DNA MARKERS"

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This application is a Divisional of U.S. Serial No. 09/018,584 filed under 37 CFR 1.53(b). Prior to examination on the merits, please amend the subject application as follows:

IN THE CLAIMS:

Please cancel claims 1-21.

Please amend the following claims to read as follows:

22. (Amended) A method for detecting a target intermediate tandem repeat DNA sequence having a low incidence of stutter artifacts, comprising the steps of:

(a) providing a sample of DNA having at least one target intermediate tandem repeat sequence, wherein the target intermediate tandem repeat sequence is a region of the DNA containing at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times; and

(b) amplifying the target intermediate tandem repeat sequence using at least one oligonucleotide primer, comprising a sequence which is complementary to and flanks a region of a double-stranded DNA marker containing a template intermediate tandem repeat sequence, wherein the template intermediate tandem repeat sequence is a region of the DNA marker which contains the repeat unit sequence repeated in tandem at least two (2) times, provided that the DNA marker has a sequence selected from the group consisting of SEQ ID NO:28, SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43; and

(c) detecting the target intermediate tandem repeat sequence in the sample of DNA, wherein an average stutter artifact of no more than 2.4% is observed.

24. (Amended) The method of claim 22, wherein the stutter artifact is observed in step (b) by comparing the target intermediate tandem repeat sequence detected to fragments of known length in a DNA size marker.

26. (Amended) A method for detecting at least one target intermediate tandem repeat sequence in a DNA sample, wherein the target intermediate tandem repeat sequence is a region of the DNA sample which contains at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times; the method comprising the steps of:

(a) providing at least one oligonucleotide primer comprising a nucleic acid sequence which is complementary to and flanks a region of a DNA marker containing a template intermediate tandem repeat sequence, wherein the DNA marker has a sequence selected from the group of sequences consisting of SEQ ID NO:28, SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43;

(b) providing a DNA sample comprising the target intermediate tandem repeat sequence;

(c) using the at least one oligonucleotide primer to amplify the target intermediate repeat sequence of the DNA sample; and

(d) detecting polymorphisms in the amplified target intermediate tandem repeat sequence.

30. (Amended) The method of claim 26, wherein the oligonucleotide primer provided in step (a) comprises a sequence selected from one of the groups of sequences consisting of:

SEQ ID NO:116 and SEQ ID NO:117, when the DNA marker sequence is SEQ ID NO:28;

SEQ ID NO:124 and SEQ ID NO:125, when the DNA marker sequence is SEQ ID NO:32;

SEQ ID NO:132 and SEQ ID NO:133, when the DNA marker sequence is SEQ ID NO:36;

SEQ ID NO:134 and SEQ ID NO:135, when the DNA marker sequence is SEQ ID NO:37;

SEQ ID NO:136 and SEQ ID NO:137, when the DNA marker sequence is SEQ ID NO:38;

SEQ ID NO:138 and SEQ ID NO:139, when the DNA marker sequence is SEQ ID NO:39;

SEQ ID NO:140 and SEQ ID NO:141, when the DNA marker sequence is SEQ ID NO:40;

SEQ ID NO:142 and SEQ ID NO:143, when the DNA marker sequence is SEQ ID NO:41;

SEQ ID NO:144 and SEQ ID NO:145, when the DNA marker sequence is SEQ ID NO:42; and

SEQ ID NO:146 and SEQ ID NO:147, when the DNA marker sequence is SEQ ID NO:43.

31. (Amended) A kit for the detection of at least one target intermediate tandem repeat sequence in a sample of DNA, wherein the target intermediate tandem repeat sequence is a region of the sample of DNA which contains at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times comprising:

a container which has at least one oligonucleotide primer for amplifying the at least one target intermediate tandem repeat sequence, wherein the oligonucleotide primer comprises a sequence of nucleic acids which is complementary to and flanks a region of a double-stranded DNA marker containing a template intermediate tandem repeat sequence comprising the repeat unit repeated in tandem at least two (2) times; and wherein the DNA marker has a sequence selected from the group consisting of SEQ ID NO:28, SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43.

See attached sheet for a marked up versions of the amended claims, provided in accordance with 37 CFR §1.121(c)(1)(ii).

REMARKS

Claims 22-34 remain pending in the present application, claims 1-21 having been canceled by amendment as described herein above.

Claims 1 through 16 were canceled, without prejudice, in prosecution of co-pending U.S. Patent Application Serial Number 09/018,548 (hereinafter, "the parent application") in response to a restriction requirement, mailed June 18, 1999 (Paper No. 5). In the interest of expediting prosecution of the remaining pending claims, Applicants hereby cancel the same set of claims herein, without prejudice to introduction of the claims in a divisional or continuation of the present application.

Claim 22 has also been amended to convert the claim into independent form by incorporating limitations from claims 17 and 21, from which it depended in the parent application. Claims 17 through 21 have been canceled herein, as being moot in view of the amendments to claim 22.

Applicants have also amended claims 22, 26, 30 and 31 herein to cancel subject matter elected, with traverse, in prosecution of the parent application. Specifically, Applicants have amended the claims cited above to cancel marker SEQ ID NOS 1-27, 33, and 34 and SEQ ID NOS for all primers identified in the application as being complementary to those particular marker sequences (i.e., SEQ ID NOS 44-115, and 126-129). The same claims have also been amended to cancel marker SEQ ID NOS 29-31, and 35 and primers identified in the application as being complementary to those particular marker sequences (i.e., SEQ ID NOS 118-123, and 130-131). The second set of markers and primer sequences were canceled due to inadvertent errors in the sequences.

Applicants submit that no new matter has been added to the application through any of the amendments introduced to the specification or claims herein.

SUMMARY

The Applicants believe that claims 22-34, after amendment as described above, are in condition for allowance, and respectfully solicit an early notice of allowance. In the event that there are any issues which can be expedited by telephone conference, the Examiner is invited to telephone the undersigned at the number indicated below.

Respectfully submitted,

Karen B King

Karen B. King
Reg. No. 41,898

Docket No.: 16026-9180
Michael Best & Friedrich LLP
One South Pinckney Street
P.O. Box 1806
Madison, WI 53701-1806

MARKED VERSION OF AMENDED CLAIMS UNDER 37 CFR § 1.121(c)(1)(ii)

All the words, phrases, or numbers added to the claims are underlined, and all words, phrases, or numbers removed from each such claim are enclosed in brackets ("[ ]").

22. (Amended) A method for detecting a target intermediate tandem repeat DNA sequence having a low incidence of stutter artifacts, comprising the steps of:

(a) providing a sample of DNA having at least one target intermediate tandem repeat sequence, wherein the target intermediate tandem repeat sequence is a region of the DNA containing at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times; and

(b) amplifying [The method of claim 21, wherein] the target intermediate tandem repeat sequence [is amplified] using at least one oligonucleotide primer, comprising a sequence which is complementary to and flanks a region of a double-stranded DNA marker containing a template intermediate tandem repeat sequence, wherein the template intermediate tandem repeat sequence is a region of the DNA marker which contains the repeat unit sequence repeated in tandem at least two (2) times, provided that the DNA marker has a sequence selected from the group consisting of [SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27,] SEQ ID NO:28, [SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31,] SEQ ID NO:32, [SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO:35,] SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43[.]; and

(c) detecting the target intermediate tandem repeat sequence in the sample of DNA, wherein an average stutter artifact of no more than 2.4% is observed.

24. (Amended) The method of claim 22 [17], wherein the stutter artifact is observed in step (b) by comparing the target intermediate tandem repeat sequence detected to fragments of known length in a DNA size marker.

26. (Amended) A method for detecting at least one target intermediate tandem repeat sequence in a DNA sample, wherein the target intermediate tandem repeat sequence is a region of the DNA sample which contains at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times; the method comprising the steps of:

(a) providing at least one oligonucleotide primer comprising a nucleic acid sequence which is complementary to and flanks a region of a DNA marker containing a template intermediate tandem repeat sequence, wherein the DNA marker has a sequence selected from the group of sequences consisting of [SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27,] SEQ ID NO:28, [SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31,] SEQ ID NO:32, [SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO:35,] SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43;

(b) providing a DNA sample comprising the target intermediate tandem repeat sequence;

(c) using the at least one oligonucleotide primer to amplify the target intermediate repeat sequence of the DNA sample; and

(d) detecting polymorphisms in the amplified target intermediate tandem repeat sequence.

30. (Amended) The method of claim 26, wherein the oligonucleotide primer provided in step (a) comprises a sequence selected from one of the groups of sequences consisting of:

[SEQ ID NO:44 and SEQ ID NO:45, when the DNA marker sequence is SEQ ID NO: 1;

SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53, SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:57, and SEQ ID NO: 58, when the DNA marker sequence is SEQ ID NO:2;

SEQ ID NO:59 and SEQ ID NO:60, when the DNA marker sequence is SEQ ID NO:3;

SEQ ID NO:61 and SEQ ID NO:62, when the DNA marker sequence is SEQ ID NO:4;

SEQ ID NO:63 and SEQ ID NO:64, when the DNA marker sequence is SEQ ID NO:5;

SEQ ID NO:65 and SEQ ID NO:66, when the DNA marker sequence is SEQ ID NO:6;

SEQ ID NO:67 and SEQ ID NO:68, when the DNA marker sequence is SEQ ID NO:7;

SEQ ID NO:69 and SEQ ID NO:70, when the DNA marker sequence is SEQ ID NO:8;

SEQ ID NO:71 and SEQ ID NO:72, when the DNA marker sequence is SEQ ID NO:9;

SEQ ID NO:73 and SEQ ID NO:74, when the DNA marker sequence is SEQ ID NO:10;

SEQ ID NO:75 and SEQ ID NO:76, when the DNA marker sequence is SEQ ID NO:11;

SEQ ID NO:77 and SEQ ID NO:78, when the DNA marker sequence is SEQ ID NO:12;

SEQ ID NO:79 and SEQ ID NO:80, when the DNA marker sequence is SEQ ID NO:13;

SEQ ID NO:81 and SEQ ID NO:82, when the DNA marker sequence is SEQ ID NO:14;

SEQ ID NO:83 and SEQ ID NO:84, when the DNA marker sequence is SEQ ID NO:15;

SEQ ID NO:85 and SEQ ID NO:86, when the DNA marker sequence is SEQ ID NO:16;

SEQ ID NO:87 and SEQ ID NO:88, when the DNA marker sequence is SEQ ID NO:17;

SEQ ID NO:89 and SEQ ID NO:90, when the DNA marker sequence is SEQ ID NO:18;

SEQ ID NO:91, SEQ ID NO:92, SEQ ID NO:93 and SEQ ID NO:94, when the DNA marker sequence is SEQ ID NO:19;

SEQ ID NO:95 and SEQ ID NO:96, when the DNA marker sequence is SEQ ID NO:20;

SEQ ID NO:97 and SEQ ID NO:98, when the DNA marker sequence is SEQ ID NO:21;

SEQ ID NO:99 and SEQ ID NO:100, when the DNA marker sequence is SEQ ID NO:22;

SEQ ID NO:101 and SEQ ID NO:102, when the DNA marker sequence is SEQ ID NO:23;

SEQ ID NO:103 and SEQ ID NO:104, when the DNA marker sequence is SEQ ID NO:24;

SEQ ID NO:105 and SEQ ID NO:106, when the DNA marker sequence is SEQ ID NO:25;

SEQ ID NO:107, SEQ ID NO:108, SEQ ID NO:109, SEQ ID NO:110 and SEQ ID NO:111, when the DNA marker sequence is SEQ ID NO:26;

SEQ ID NO:112, SEQ ID NO:113, SEQ ID NO:114 and SEQ ID NO:115, when the DNA marker sequence is SEQ ID NO:27;]

SEQ ID NO:116 and SEQ ID NO:117, when the DNA marker sequence is SEQ ID NO:28;

[SEQ ID NO:118 and SEQ ID NO:119, when the DNA marker sequence is SEQ ID NO:29;

SEQ ID NO:120 and SEQ ID NO:121, when the DNA marker sequence is SEQ ID NO:30;

SEQ ID NO:122 and SEQ ID NO:123, when the DNA marker sequence is SEQ ID NO:31;]

SEQ ID NO:124 and SEQ ID NO:125, when the DNA marker sequence is SEQ ID NO:32;

[SEQ ID NO:126 and SEQ ID NO:127, when the DNA marker sequence is SEQ ID NO:33;

SEQ ID NO:128 and SEQ ID NO:129, when the DNA marker sequence is SEQ ID NO:34;

SEQ ID NO:130 and SEQ ID NO:131, when the DNA marker sequence is SEQ ID NO:35;]

SEQ ID NO:132 and SEQ ID NO:133, when the DNA marker sequence is SEQ ID NO:36;

SEQ ID NO:134 and SEQ ID NO:135, when the DNA marker sequence is SEQ ID NO:37;

SEQ ID NO:136 and SEQ ID NO:137, when the DNA marker sequence is SEQ ID NO:38;

SEQ ID NO:138 and SEQ ID NO:139, when the DNA marker sequence is SEQ ID NO:39;

SEQ ID NO:140 and SEQ ID NO:141, when the DNA marker sequence is SEQ ID NO:40;

SEQ ID NO:142 and SEQ ID NO:143, when the DNA marker sequence is SEQ ID NO:41;

SEQ ID NO:144 and SEQ ID NO:145, when the DNA marker sequence is SEQ ID NO:42; and

SEQ ID NO:146 and SEQ ID NO:147, when the DNA marker sequence is SEQ ID NO:43[;].

31. (Amended) A kit for the detection of at least one target intermediate tandem repeat sequence in a sample of DNA, wherein the target intermediate tandem repeat sequence is a region of the sample of DNA which contains at least one repeat unit consisting of a sequence of five (5), six (6), or seven (7) base pairs repeated in tandem at least two (2) times comprising:

a container which has at least one oligonucleotide primer for amplifying the at least one target intermediate tandem repeat sequence, wherein the oligonucleotide primer comprises a sequence of nucleic acids which is complementary to and flanks a region of a double-stranded DNA marker containing a template intermediate tandem repeat sequence comprising the repeat unit repeated in tandem at least two (2) times; and wherein the DNA marker has a sequence selected from the group consisting of [SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27,] SEQ ID NO:28,[SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31,] SEQ ID NO:32, [SEQ ID NO: 33, SEQ ID NO: 34, SEQ ID NO:35,] SEQ ID NO:36,

SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, and SEQ ID NO:43.